

ATTACHMENT 2

Preliminary Proposed Criteria Discussed at Public Meeting

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Normally, in considering a proposed rulemaking action, the NRC performs an aggregate regulatory analysis for the entire rule to determine whether or not it is justified. However, there is a concern that aggregation or bundling of different requirements in a single analysis could potentially mask the inclusion of an inappropriate individual requirement. In the case of a rule that provides a voluntary alternative to current requirements, the net benefit from relaxation of one requirement could potentially support an unrelated requirement that is not cost-justified. In the case of a rule that is subject to a backfit analysis, the net benefit from one requirement could potentially support an unrelated requirement that is not cost-justified.¹ To address this concern, in presenting a rulemaking alternative that constitutes an aggregation or bundling of requirements, the analyst should include an individual requirement only if it is integral to the purpose of the rule or justified on a cost-benefit basis.

In this context, an individual requirement is considered integral to the purpose of the rule if it is:

- (1) Necessary to achieve the stated objectives of the rule;
- (2) Needed, in combination with other elements of the rule, to establish a coherent regulatory approach, such as the key principles discussed in Regulatory Guide 1.174;²
- (3) Not separable from other elements of the rule; or

¹This discussion does not apply to backfits that qualify under one of the exceptions in 10 CFR 50.109(a)(4) (i.e., backfits that are necessary for compliance or adequate protection). Those types of backfits require a documented evaluation rather than a backfit analysis, and cost is not a consideration in deciding whether or not they are justified.

²Regulatory Guide 1.174, "An Approach for Using Probabilistic Risk Assessment In Risk-Informed Decisions On Plant-Specific Changes to the Licensing Basis," July 1998, includes five key principles, four of which would be appropriate to consider in connection with a risk-informed voluntary alternative rule:

- (1) The proposed change is consistent with the defense-in-depth philosophy;
- (2) The proposed change maintains sufficient safety margins;
- (3) If there is an increase in core damage frequency or risk, it should be small and consistent with the intent of the NRC's safety goal policy statement, published in the Federal Register on August 4, 1986 (51 FR 30028); and
- (4) The impact of the proposed change should be monitored using performance measurement strategies.

(4) Needed to ensure that the rule does not significantly increase risk. As an example of this category, if a rule provides a relaxation in one requirement for the purpose of reducing unnecessary burden, a compensating increase in another requirement might be needed to support a finding that risk is not significantly increased.

If an individual requirement is not integral to the purpose of the rule, it must be cost-justified. This means that the individual requirement must add more to the rulemaking action in terms of benefit than it does in terms of cost. It does not mean that the individual requirement, by itself, must provide a substantial increase in the overall protection of the public health and safety or the common defense and security.

As a practical matter, a rulemaking action is generally divided into discrete elements for the purpose of estimating costs and benefits in a regulatory analysis. Thus, it should be apparent to the analyst whether or not there are individual elements that must be excluded because they are neither integral to the purpose of the rule nor cost-justified. The analyst may rely on his or her judgment to make this determination. It is not necessary to provide additional documentation or analysis to explain how the determination was made.

When a draft regulatory analysis is published for comment along with a proposed rule, the NRC may receive a comment to the effect that an individual requirement is neither integral to the purpose of the rule nor cost justified. If the comment provides a reasonable indication that this is the case, the NRC's response in the final rule should either agree with the comment or explain how, notwithstanding the comment, the individual requirement is determined to be integral to the purpose of the rule or cost-justified. To provide a reasonable indication, the comment must:

- (1) Identify the specific regulatory provision that is of concern;
- (2) Explain why the provision is not integral to the purpose of the rule, with supporting information as necessary; and

(3) Demonstrate, with supporting information, that the regulatory provision is not cost-justified.

Comments that do not provide a reasonable indication need not be addressed in detail.³

A special case involves the NRC's periodic review and endorsement of new versions of the ASME Codes. Some aspects of those rulemakings are not addressed in regulatory analyses. However, for those matters that are addressed in regulatory analyses, the same principles as discussed above should be applied. Further details are provided below.

The NRC's longstanding policy has been to incorporate new versions of the ASME Codes into its regulations. Furthermore, the National Technology Transfer and Advancement Act of 1995 (Public Law 104-113) directs Federal agencies to adopt technological standards developed by voluntary consensus standard organizations. The law allows an agency to take exception to specific portions of the standard if those provisions are deemed to be inconsistent with applicable law or otherwise impractical.

ASME Codes are updated on an annual basis to reflect improvements in technology and operating experience. The NRC reviews the updated ASME Codes and conducts rulemaking to incorporate the latest versions by reference into 10 CFR 50.55a, subject to any modifications, limitations, or supplementations (i.e., exceptions) that are deemed necessary.⁴ It is generally not necessary to address new provisions of the updated ASME Codes in the regulatory analyses for these rulemakings. However:

(1) When the NRC endorses a new provision of the ASME Code that takes a substantially different direction from the currently existing requirement, the action should be

³NUREG/BR-0053, Revision 5, March 2001, "United States Nuclear Regulatory Commission Regulations Handbook," Section 7.9, provides further discussion of comments that should be treated in detail.

⁴ NRC regulations require licensees to periodically update their inservice inspection and inservice testing programs to the latest ASME Code incorporated by reference in 10 CFR 50.55a(b).

addressed in the regulatory analysis. An example was the NRC's endorsement of new Subsections IWE and IWL, which imposed containment inspection requirements on operating reactors for the first time. Since those requirements involved a substantially different direction, they were considered in the regulatory analysis, treated as backfits, and justified in accordance with the standards of 10 CFR 50.109.

(2) If the NRC takes exception to a new Code provision and imposes a requirement that is a substantial change from the currently existing requirement, the action should be addressed in the regulatory analysis.

(3) When the NRC requires implementation of a new Code provision on an expedited basis, the action should be addressed in the regulatory analysis. This applies when implementation is required sooner than it would be required if the NRC simply endorsed the Code without any expediting language.

When the NRC takes exception to a new Code provision, but merely maintains the currently existing requirement, it is not necessary to address the action in the regulatory analysis (or to justify maintenance of the status quo on a cost-benefit basis). However, the NRC explains any exceptions to the ASME Code in the Statement of Considerations for the rule.